

**Remarks**

The Application has been reviewed in light of the Official Action of January 23, 2009. Claims 25-38, 40-48, 50 and 51 are pending in the Application.

The Examiner has rejected claims 25, 26, 33, 38, 40-42, 44, 46 and 50 under 35 U.S.C. 103(a) as being unpatentable over Morrison (US 4,522,832). The Examiner has rejected claims 25-38, 40-48, 50 and 51 under 35 U.S.C. 103(a) as being unpatentable over Bell et al. (US 5,902,797) in view of Martinez et al. (J Dairy Sci. 1998, 71, 893-900), the Merck Manual, Mahmoud et al. (US 5,104,676), Hsia (US 6,294,166) and Acosta et al. (US 5,550,146).

**Claim 25**

Morrison discloses:

incorporating lactase enzyme into baking formulations for producing yeast leavened products which formulations include sugar and a lactose-containing dairy product, such as whey, as a protein supplement. During the dough processing, the lactose is converted into baker's yeast-fermentable glucose and galactose and consequently, the amount of expensive sugar substrate usually added to such formulations to provide food for the yeast may be generally reduced.

(Abstract)

As recognized by the Examiner, Morrison does not teach a method for reducing energy deficit in a mammal by administering an energy promoting effective amount of a composition having less than 3% fat. The Examiner references Example I of Morrison and concludes that Morrison teaches administering a composition with about 1% to about 5 % by weight of lactase. However, Example I of Morrison is a baking formulation that is processed to form bread. Morrison discloses that during such processing the lactase converts lactose in to the simple sugars glucose and galactose. Morrison does not disclose that the bread formed after such a process comprises about 1% to about 5 % by weight of lactase. Further, Morrison does not disclose administering the baking formulation of Example 1. As a result, in addition to not disclosing a method for reducing energy deficit in a mammal by administering an energy promoting effective amount of a composition having less than 3% fat, Applicants respectfully submit that Morrison also does not disclose administering a composition that comprises a protein component with about 1% to about 5 % by weight of lactase.

Bell discloses a dietary supplement that provides nutritional support for children with attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD) that includes components: carbohydrate, from about 5 to about 25 grams; protein, from about 1 to about 25 grams; and fat, from about 1 to about 10 grams. As recognized by the Examiner, Bell does not disclose a method for reducing energy deficit in a mammal using a composition that comprises a protein component with about 1% to about 5 % by weight of lactase.

The Examiner identifies Martinez et al. as teaching that whey powder has lactose and the Merck Manual as teaching adding lactase to convert lactose to glucose and galactose. Applicants would like to bring to the Examiner's attention that the Merck Manual specifically teaches adding lactase to milk and that the lactase breaks down the lactose in the milk before the person drinks it. Thus, like Morrison and other references previously cited by the Examiner, such as Schlothauer et al. and Mahmoud et al., the Merck Manual discloses adding lactase to break down lactose, however the Merck Manual also does not disclose administering a composition that comprises a protein component with lactase, let alone about 1% to about 5 % by weight of lactase.

Applicants respectfully submit that Claim 25 is not obvious in view of each of the references cited by the Examiner because these references do not disclose nor fairly suggest each and every element of claim 25. It is well settled that to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). As discussed above, each of the references cited by the Examiner do not disclose a method for reducing energy deficit in a mammal by administering a composition that comprises a protein component with about 1% to about 5 % by weight of lactase. This required step and composition is not disclosed by the cited references and as a result, these references do not provide a basis to conclude that one skilled in the art would modify any method therein to correspond to claim 25. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741 (2007) ("it can be important to identify a reason that would have

prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does”).

The Examiner asserts that one skilled in the art would be motivated to use the bread in Morrison to reduce the energy deficit in and provide critical care for a mammal. While Morrison provides no indication that the bread disclosed therein could be used to provide critical care for a mammal, even if the Examiner's conclusion were assumed to be correct, such a use of the bread in Morrison would still not result in the claimed invention. Claim 25 requires a method for reducing energy deficit in a mammal by administering a composition that comprises a protein component with about 1% to about 5 % by weight of lactase. While Morrison does disclose a baking formulation that is processed to form bread, Morrison also discloses that during such processing the lactase converts lactose in to the simple sugars glucose and galactose. Thus, Morrison does not disclose that the bread formed after such a process comprises about 1% to about 5 % by weight of lactase. As a result, even if the bread in Morrison were administered to reduce the energy deficit in and provide critical care for a mammal, claim 25's requirement of administering a composition that comprises a protein component with about 1% to about 5 % by weight of lactase would still not be performed.

The Examiner also asserts that one skilled in the art would be motivated to modify the nutritional supplement disclosed in Bell by adding lactase in the manner disclosed in the Merck Manual. Even if the Examiner's conclusion were assumed to be correct, such a modification of the dietary supplement disclosed in Bell would still not result in the claimed invention. Claim 25 requires a method for reducing energy deficit in a

mammal by administering a composition that comprises a protein component with about 1% to about 5 % by weight of lactase. While the Merck Manual does disclose adding lactase to milk, the Merck Manual also discloses that the lactase breaks down the lactose in the milk before the person drinks it. Thus, the Merck Manual, like Morrison, does not disclose administering to a mammal a composition comprising lactase, let alone a composition comprising about 1% to about 5 % by weight of lactase. As a result, even if the dietary supplement disclosed in Bell were modified to include lactase in the manner disclosed in the Merck Manual, claim 25's requirement of administering a composition that comprises a protein component with about 1% to about 5 % by weight of lactase would still not be performed.

In view of the foregoing, Applicants respectfully submit that claim 25 is not obvious in view of the cited references.

#### Claim 50

Claim 50 provides a method of "providing critical care to a mammal with an energy deficiency by reducing the energy deficiency in the mammal" by "administering to the mammal a diet consisting of a critical care feeding program that consists of an energy promoting effective amount of a composition having less than 3% fat..." As a result, this claim requires that a mammal with an energy deficit be provided with a diet that consists of a feeding program and that the feeding program consists of a composition having less than 3% fat.

In rejecting this claim, the Examiner does not identify where Morrison, Bell or any other reference of record disclose these requirements or provide a reason why it would be obvious to modify methods disclosed in Morrison or Bell in accordance with Claim 50.

As discussed above, Morrison only discloses a baking formulation that is processed to form bread. Morrison does not disclose “administering to the mammal a diet consisting of a critical care feeding program”, let alone “a critical care feeding program that consists of an energy promoting effective amount of a composition having less than 3% fat...” Applicants respectfully submit that the Examiner’s rejection does not address these requirements and does not identify any factual basis for concluding that one skilled in the art would modify the method in Morrison in accordance with claim 50. *KSR Int’l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741 (2007) (“it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does”). Applicants further submit that Morrison in fact does not provide a basis to conclude that one skilled in the art would perform the method of “providing critical care to a mammal with an energy deficiency by reducing the energy deficiency in the mammal” by “administering to the mammal a diet consisting of a critical care feeding program that consists of an energy promoting effective amount of a composition having less than 3% fat...” Morrison is simply silent with respect to these limitations.

Similarly, with respect to Bell, the Examiner’s rejection does not identify where Bell or any other cited reference disclose the method of “providing critical care to a

mammal with an energy deficiency by reducing the energy deficiency in the mammal” by “administering to the mammal a diet consisting of a critical care feeding program that consists of an energy promoting effective amount of a composition having less than 3% fat...” The Examiner’s rejection simply does not identify any factual basis for concluding that one skilled in the art would modify the method in Bell to correspond to claim 50. *KSR Int’l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741 (2007) (“it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does”). Applicants further submit that Bell, like other references previously cited by the Examiner, such as Mahmoud et al., in fact teaches away this claimed method. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). As noted above, Bell teaches using the composition disclosed therein as a nutritional supplement, i.e. the composition disclosed therein is administered in addition to the regular diet of the child. Such a disclosure teaches one skilled in the art that the disclosed composition can be used to supplement a child’s diet, but the child’s diet does not consist of the disclosed composition. As a result, Bell discourages one skilled in the art from modifying the disclosed method in accordance with claim 50.

The present Application provides a method for providing critical care to a mammal with an energy deficiency. The specification of the present Application provides a specific example of the claimed method providing critical care to a mammal:

A 6 year old, 100 kg, American Miniature Horse presented to the  
Veterinary Teaching Hospital with a 3 day history of anorexia, depression,

and ventral edema. She was nursing a healthy five week old foal at the time of presentation. Initial physical examination showed weakness, reluctance to move, elevated pulse and respiratory rate, and ileus. CBC and blood chemistry profile showed azotemia, hypocalcemia, metabolic acidosis, and elevated liver enzymes and total bilirubin. A serum triglyceride concentration was greater than 2000 mg/dl. Based on the above findings a diagnosis of hyperlipemia and hepatic lipidosis was made. Initial treatment consisted of intravenous polyionic fluids to correct the azotemia and provide maintenance fluids. Intravenous dextrose was provided to correct the negative energy balance. Subcutaneous heparin and insulin were given to treat the hyperlipemia. Despite aggressive medical therapy, the mare developed signs of hepatoencephalopathy including circling, muscle fasciculations and severe depression, corresponding to elevated blood ammonia. On day 2 of hospitalization, a nutrition consultation was performed. A three-stage ration was formulated based on the mare's requirements for digestible energy, crude protein, calcium, and magnesium for maintenance and lactation. The predetermined diet was low in fat and protein, but provided enough calories to decrease the utilization of body fat. The diet was delivered through a small-bore nasogastric tube every 2-4 hours. Each stage was given for 24 hours and by the third day of oral feedings the neurologic signs had disappeared and the serum triglyceride concentration had



decreased to within normal range. The liver enzymes and total bilirubin were also decreasing. She began eating on day six of hospitalization and the enteral feedings were discontinued. She was discharged on day 8 after presentation with instructions to provide supplemental feedings for the next 3 weeks and to wean the foal to decrease the energy demands on the mare. A follow-up visit performed 4 weeks after discharge showed no significant abnormalities on physical examination and a continued decrease in the serum concentration of liver enzymes. (App. Par. [0115]).

Providing a diet that consists of a critical care feeding program that consists of an energy promoting effective amount of a composition having less than 3% fat decreases "hepatic lipodosis and the amount of processing the liver must perform to make energy available to somatic cells." (App. Par. [0103]). "The total program has a fat content of less than 3% so that it can be used in the face of compromised (or underdeveloped) liver function." (App. Par. [0106]). Further, this diet enables practitioners to "target specific needs and metabolic conditions. Providing a low fat nutraceutical composition has been found to improve the long-term prognosis for recovery and can be done both simply and cost effectively." (App. Par. [0006]). This is not taught, suggested or recognized by Morrison or Bell and neither reference provides a basis to conclude that one skilled in the art would modify the methods in either reference to correspond to the Claim 50.

In view of the foregoing, Applicants respectfully submit that Claim 50 is not obvious in view of the cited references.

For the foregoing reasons, Applicants respectfully submit that all pending claims are patentable over the references of record, and earnestly solicits allowance of the same.

Respectfully submitted,

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/Wesley W. Whitmyer, Jr./

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